

ADDITIONAL FEES

Four (4) additional independent claims and five (5) additional claims in excess of 20 are being filed herein and the Small Entity Fees therefor are \$200.00 [\$39 times 4=\$156 plus \$9 times 5 =\$45 for a total of \$200.00]. A check in the amount of \$200.00 is being enclosed herewith to pay the additional claim fees for Claims 39 through 43 being filed herein.

No additional fees are deemed due herein. However, if any additional fees are required for any reason, please charge the same to Deposit Account No. 13-2515.

REMARKS**Claims**

Claims 1 through 38 are pending in the Application and new Claims 39 through 43 are being added by amendment.

Claims 21 through 28 have been allowed.

Claims 1-20 and 29-32 have been rejected.

Claims 19, 30 and 33 would be allowable if re-written to include all of the limitations of the base claim and any intervening claims. The subject matter of these claims including all of the limitations of the base claims have been included in new claims 39, 40 and 41, respectively.

New claim 42 and dependent claim 43 are based on the structure of claim 20, as amended herein.

**Drawing**

The Examiner has approved the drawings as corrected and all objections to the drawings have been withdrawn.

**Specification**

The Examiner has withdrawn all prior objections to the drawing.

**Claim Objections**

The Examiner brought to Applicant's attention that Claims 32 through 37 were misnumbered and have been renumbered as Claims 33 through 38.

Applicant agrees with the Examiner remarks. As noted in the above amendments to Claims 33 through 38, the dependent claims have been amended to depend from the properly numbered independent claims.

Claim 33 has been amended to correct the grammar and verb tense such that the claim now reads as a sentence.

Claim 38 has been corrected to replace the word "slop" with the word --slope--.

**Claim Rejections - 35 USC § 112**

The Examiner has withdrawn all prior rejections under 35 U.S.C. 112.

**Claim Rejections - 35 USC §102**

The Examiner rejected claims 1 through 4 under 35 U.S.C. § 102(b) as being anticipated by Guena et al. United States Patent 5,417,651.

In making this rejection, the Examiner stated that depending upon the angle in which the implant is inserted, the elongated member positions the exterior surface away from a surface of an eye.

In Paragraph 15 of the Office Action, the Examiner noted that certain features of Applicant's invention being relied upon by Applicant have not been recited in the rejected claims; namely that the lip extends or protrudes beyond the outer surface of the elongated member is located around approximately 300 degrees or less of the periphery of the elongated member leaving the

posterior free from protruding into, or from contacting with or abrading the surface of an eye including the cornea or conjunctiva.

Bearing the above in mind, Claim 1 has been amended to now recite the feature being relied upon by Applicant in distinguishing the present invention over the prior art:

a thin elongated lip which protrudes beyond the outer surface of the elongated member and is located approximately 300 degree or less of the periphery of the elongated member leaving a posterior surface free from protruding into or from contacting with or abrading a surface of the eye including the cornea or conjunctiva [Underlining added to show amendatory language.]

Again, Applicant emphasis that Guena et al. discloses and teaches at column 2, lines 60 through 65, to wit:

The flange 3 is tilted relative to the axis of symmetry X of the plug. The tilting of the flange allows [the flange] to have full contact between the cornea and the flange thereby avoiding irritation [Underlining added for emphasis].

and Guena et al. anticipates that, when the lacrimal occluder is implanted into the eye, the flange contacts the surface of the eye.

As such the amendatory language as set forth above clearly and sharply distinguishes the present invention from the disclosure of Guena et al and clearly provides structure which positions the thin elongated lip away from a surface of an eye.

For all of the above reasons, the Examiner's rejection Claims 1-4, as amended, under 35 U.S.C. § 102(b) as anticipated by Guena et al. United States Patent 5,417,651, has been overcome.

The Examiner rejected Claims 1 through 3 and 18 under 35 U.S.C. § 102(b) as being anticipated by Seder et al United States Patent 4,959,048.

As discussed above, independent Claim 1 has been amended to recite that:

"\* \* \* a thin elongated lip which protrudes beyond the outer surface of the elongated member and is located approximately 300 degree or less of the periphery of the elongated member leaving a posterior surface free from protruding into or from contacting with or abrading a surface of the eye including the cornea or conjunctiva \* \* \*".

This amendatory language clearly provides structure which positions the thin elongated lip away from a surface of an eye.

Independent Claims 5 and 18 have been similarly amended.

For all of the above reasons, the Examiner's rejection of Claims 1-3, 5 and 18, as amended, under 35 U.S.C. § 102(b) as anticipated by Seder et al United States Patent 4,959,048, has been overcome.

The Examiner withdrew the indicated allowability of Claim 20 in view of Tajiri, United States Patent 5,423,777. The basis for the Examiner's rejection is as follows:

Claim 20 is rejected under 35 U.S.C. 102(e) as being anticipated by Tajiri et al U.S. Patent 5,423,777) for the following reasons: With respect to claim 20, See Figures 1 and 2 for a punctum plug (10) wherein the tip insertion section gently expands to a generally oval shape.

The Examiner's rejection of Claim 20 under 35 U.S.C. 102(e) in view of Tajiri, United States Patent 5,423,777 is respectfully traversed for several important reasons.

A careful reading of Tajiri, United States Patent 5,423,777 at column 4, lines 22 through 25 discloses the following description of how the bulb portion stretches and elongates to pass into the duct:

As the plug 10 is pushed into one of the ducts 38 and 40, the bulb portion 18 stretches and elongates as illustrated in Fig. 2, which facilitates pushing the plug 10 into the duct.

Claim 20 claims a lacrimal occluder in the form of an implant having a tip insertion section (which may be collapsible but still retain sufficient rigidity to dilate the punctum opening) that functions to gently expand the sphincter muscle defining the punctum opening into a generally oval shape.

In the punctum plug disclosed by Tajiri, United States Patent 5,423,777, the bulb portion functions in an opposite manner, that is, the bulb portion 18 stretches and elongates as illustrated in Fig. 2, which facilitates pushing the plug 10 into the duct.

As such, the implant claimed in Claim 20 is structurally different that a bulb portion that stretches and elongates to facilitate pushing the plug into the duct.

In order to provide clarity and to remove any ambiguity that it is the sphincter muscle defining the punctum opening that is gently expanded into a predetermined shape, such as for example, a generally oval shape, claim 20 has been amended as follows;

20. (Amended) An implant comprising  
an elongated member having a pair of  
ends wherein one of said pair of ends  
terminates in a tip insertion section having  
a distal starting tip having a cross-  
sectional dimension that penetrates a punctal  
opening defined by a fibrous tissue and  
wherein said distal starting tip has a  
selected length to pass through the punctal  
opening to enable the tip insertion section  
to gently expand [to a generally oval shape]  
the sphincter muscle defining the punctum  
opening into a generally oval shape.

For all of the above reasons, the Examiner's rejection of Claim 20 under 35 U.S.C. 102(e) in view of Tajiri, United States Patent 5,423,777 has been overcome.

Th Examiner's Attention is directed to new claims 42 and 43 which are based on Claim 20, as amended. Claim 42 is directed to a lacrimal occluder comprising a tip insertion section in the form of a collapsible flared section and having a distal starting tip and wherein the tip insertion section gently expands the sphincter muscle defining the punctum opening to a dimension and

shape sufficient for passing the tip insertion section. Claim 43 recites that the collapsible flared section is conical shaped. Of course, the conical shaped may be circular, oval, elliptical or other appropriate shape. Claims 42 and 43 are deemed to define patentable subject matter over Tajiri, United States Patent 5,423,777 for the same reasons as Claim 20.

The Examiner rejected Claims 29 and 31-32 under 35 U.S.C. § 102(b) as being anticipated by Herrick United States Patent 5,163,959. In making this rejection, the Examiner stated as follows:

- a. With respect to claim 29, 33 and 35-37, see Figure 1 and 10(b) for a punctum plug comprising an elongated member having a central member (22) with predetermined cross-sectional dimension, the member having at one end a tip insertion section (26) having an offset (i.e., beveled or angled) distal starting tip (32), the offset distal starting tip having a smaller cross-section than the tip insert section, and wherein the member has a second end which comprises a thin elongated lip (34).
- b. With respect to claims 31 and 32, see Figures 10(a) through 10(b) for the method of treating a tear deficiency with the recited punctum plug.

Applicant respectfully traverses this rejection for several important reasons.

In Herrick, United States Patent 5,163,959, the starting tip axis, as shown in Figs. 1 and 10(b), is concentric with the elongated axis and is in alignment with the tip insert section. As such, the tip insert section has an aligned starting tip. In the present invention, this is shown as Fig. 25 (f) which is labeled *PRIOR ART*.

In Figs. 26, 29, 30(a), 30(b), 30(c) 31 and 32, the starting tip axis is not concentric with the elongated axis, but is in fact offset from the tip insert section. As such, the tip insert section has an offset distal starting tip.

Claim 29 at lines 11 to 13 includes the following structural language:

wherein the tip insert section has an offset distal starting tip which is smaller in cross-sectional dimension than said tip insert section; [Underlining added for emphasis.]

Claim 31 at lines and 11 has similar structural language. Claim 32 is dependent on Claim 31, and is subject to this structure.

As such, it is very clear that Herrick United States Patent 5,163,959 does not disclose, suggest or teach a tip insert section having an offset distal starting tip nor that the offset tip has a smaller cross-sectional dimension than the tip insert section.

In addition, independent Claim 29 and 31 have been amended using the same language as in Claim 1 to provide structure which positions the thin elongated lip away from a surface of an eye

Claim 33, does not include the same structural language in that Claim 33, as amended, but does contain the following amendatory language to place a lip on the other end of the punctum plug:

and wherein the other of said pair of ends has a lip for engaging the punctum opening and positioning said enlarged annular shaped section in a canaliculus adjacent a punctual of an eye.

From the standpoint of the canalicular implant having a collapsible flared section, such an implant can function as an lacrimal occluder. A lacrimal occluder is sometimes referred to as a punctum plug or an implant. By including the amendatory language to Claim 33, the features of a collapsible flared section is combined with a lip. The lip can be of any shape, circular, flanged shaped, tilted flange or thin elongated lip including a thin elongated lip which protrudes beyond the outer surface of the elongated member and is located approximately 300 degree or less of the periphery of the elongated member leaving a posterior surface free from protruding into or from contacting with or abrading a surface of the eye including the cornea or conjunctiva. The lip engages the punctum opening and positions the enlarged annular shaped section in a canaliculus adjacent to a punctual of an eye.

Clearly this is a patentable concept, and is not disclosed by Freeman, Guena et al. or Seder et al. Although the canalicular implant disclosed in Herrick U. S. Patent 5,163,959 does not specifically disclose a structure including a lip for use for in an application commonly known as a punctum plug, punctum occluder or punctum implant, the concept as disclosed herein can be used with any type of lip, and Applicant verily believes that he is entitled to a claim covering this novel combination.

For all of the above reasons, the Examiner's rejection of Claims 29 and 31-32 under 35 U.S.C. § 102(b) as being anticipated by Herrick United States Patent 5,163,959 has been overcome.

The Examiner rejected Claims 33-37 under 35 U.S.C. § 102(b) as being anticipated by MacKeen et al (U. S. Patent 4,915,684), for the following reasons:

With respect to claims 33-37, see Figure 4 for a punctum plug having a starting tip (58) and an enlarged annular shaped section (46) at the end of a dilated opening (50) having conical flared shape with a rounded outer edge, the starting tip having an external retaining member (60).

The rejection of Claims 33-37 under 35 U.S.C. § 102(b) as being anticipated by MacKeen et al (U. S. Patent 4,915,684) is respectfully traversed for several important reasons.

First, the structure of the lacrimal fluid modulating device of MacKeen et al. is similar to that disclosed by Freeman U.S. Patent 3,949,750, namely, a solid, non-collapsible conically shaped body member.

Claim 33, as amended, sharply and clearly is directed to an enlarged collapsible annular shaped section terminating in a starting tip. This structure is not disclosed, suggested or taught by MacKeen et al.

With respect to dependent Claims 34 through 37, Applicant is not relying on a rounded edge, for example, for patentability, but is relying on the dependent claims to vary the scope of what is believed to be a patentable independent Claim 33.

For all of the above reasons, the rejection of Claims 33-37 under 35 U.S.C. § 102(b) as being anticipated by MacKeen et al (U. S. Patent 4,915,684) has been overcome.

#### **Double Patenting**

Applicant acknowledges that the Examiner has rejected Claims 1 and 4 through 17 under the judicially created doctrine of double patenting over Herrick United States Patent 5,723,005.

In order to overcome this rejection, the undersigned,, as attorney of record, signed and included with the AMENDMENT filed on March 15, 1999 a TERMINAL DISCLAIMER TO OBVIATE A DOUBLE PATENTING REJECTION OVER A PRIOR PATENT, namely, United States Patent 5,723,005, together with the Statutory Disclaimer Fee of \$55.00 required under 37 CFR 1.20(d).

Since the Examiner has not received the TERMINAL DISCLAIMER TO OBVIATE A DOUBLE PATENTING REJECTION OVER A PRIOR PATENT, enclosed herewith are copies of the following documents:

- (1) TERMINAL DISCLAIMER TO OBVIATE A DOUBLE PATENTING REJECTION OVER A PRIOR PATENT, namely, United States Patent 5,723,005; and
- (2) A check in the amount of \$55.00 paying the Statutory Disclaimer Fee of \$55.00 required under 37 CFR 1.20(d).

With the filing of the Terminal Disclaimer and Payment of the Statutory Disclaimer Fee, the Examiner's rejection of Claims 1 and 4 through 17 over Herrick United States Patent 5,723,005 under the judicially created doctrine of double patenting has been overcome.

### Response to Arguments

Applicant acknowledges and appreciates the Examiner's response to Applicant's arguments set forth in the AMENDMENT filed on March 15, 1999. As discussed hereinbefore, the Examiner noted that certain features of Applicant's invention being relied upon by Applicant had not been recited in the rejected claims; namely that the lip extends or protrudes beyond the outer surface of the elongated member is located around approximately 300 degrees or less of the periphery of the elongated member leaving the posterior free from protruding into, or from contacting with or abrading the surface of an eye including the cornea or conjunctiva.

Bearing the above in mind, the various applicable claims have been amended to now recite the features being relied upon by Applicant in distinguishing the present invention over the prior art.

Upon further consideration to the position taken by the Examiner with respect to Applicants arguments of Herrick, Applicant agrees that the recitation of "an offset distal starting tip" does broadly equate itself to a starting tip which is not concentric with the elongated axis for prior art citation with respect to Claims 1 through 43 presently in this Application, and such claims are verily believed to be patentable over the prior art.

Applicant has made a diligent effort to incorporate the suggestions and/or remarks of the Examiner into the amendatory language of the claims.

**Allowable Subject Matter**

Applicant acknowledges and appreciate the Examiner allowing Claims 21 through 28.

With respect to Claims 19, 30 and 38, these claim have been rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2<sup>nd</sup> paragraph, set forth in the prior Office Action and to include all of the limitations of the base claim and any intervening claims and the rewritten claims are included herein as new Claims 39, 40 and 41, respectively.

Claim 19, is dependent on Claim 18. Since Claim 18 is verily believed to be allowable, Claim 19 is being retained in the Application in its present condition on the basis that it varies the scope of the invention based on what is believed to be an allowable independent claim.

Claim 30 is dependent on Claim 29. Since Claim 29 is verily believed to be allowable, Claim 30 is being retained in the Application, as amended, on the basis that it varies the scope of the invention based on what is believed to be an allowable independent claim.

**New Claims 39 through 43**

Applicant has added new Claims 39 through 43 to this United States Patent Application and the additional claim fees therefor have been paid concurrently with the filing of this Amendment.

Claims 39, 40 and 41 have been rewritten as noted above to include the subject matter of Claims 19, 30 and 31, respectively, which the Examiner, as noted above, are deemed to be patentable.

New Claims 42 and 43 are based on Claim 20, and the patentability thereof have been discussed above in connection with the rejection of Claim 20.

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New Claims 39 through 43 are verily believed to define patentable subject matter for all of the reasons set forth above.

**Summary**

Claim 1 through 38, as amended, and new Claims 39 through 43 are present in the Application.

With the filing of the Terminal Disclaimer with the AMENDMENT filed March 15, 1999, the double patenting rejection has been overcome.

All of the claims presently pending in this United States Patent Application are verily believed to define patentable subject matter over the Cited Art.

For all of the above reasons, it is verily believed that this United States Patent Application is in condition for Allowance. The Examiner is respectfully requested to issue a Notice of Allowability and a formal Notice of Allowance.

Applicant will file the formal drawing, containing the corrections approved by the Examiner, on or before payment of the Issue Fee.

If the Examiner determines that further amendments to the claims would render the same allowable or would facilitate the issue of a Notice of Allowance, the undersigned respectfully requests the Examiner to call the undersigned for an interview in order to expedite the issuance of a Notice of Allowance.

Respectfully submitted,



Daniel J. Meaney, Jr.  
Registration 22179  
Attorney for Applicant

DANIEL J. MEANEY, JR., ESQ.  
P. O. Box 22307  
Santa Barbara, CA 93121  
Telephone: (805) 565-5513  
Dated: December 10, 1999  
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